K081120 Confidential

MAY - 1 2008

## 510(K) Summary

A. Submitter Information

| | |
|---|---|
| Submitter's Name: | Kettenbach GmbH & Co. KG |
| Address: | Im Heerfeld 7<br>D-35713<br>Eschenburg, Germany |
| Phone Number: | (+49) 2774-705-58 |
| Fax Number: | (+49) 2774-705-33 |
| Contact Person: | Michaela Zinke |
| Date of Preparation: | March 27, 2008 |

B. Device Name

| | |
|---|---|
| Trade Name: | *Futar® (Futar®, Futar® D, Futar® D Fast, Futar® D Slow, Futar® Scan) Bite Registration Materials* |
| Common/Usual Name: | Bite Registration Material |
| Classification Name: | Material, Impression (21 CFR 827.3660, Product Code: ELW) |

C. Predicate Devices

| | |
|---|---|
| Trade Name: | Futar® Occlusion, Futar® D Occlusion (K954281) |
| Trade Name: | R-SI-LINE® METAL-BITE® (K010926) |
| Trade Name: | Mega Bite Registration (K030776) |

D. Device Description

*Futar®, Futar® D, Futar® D Fast, Futar® D Slow,* and *Futar® Scan* are syringeable, addition-curing, elastomeric bite registration materials which differ in their final hardnesses, curing times, and linear dimensional changes.

E. Intended Use

*Futar® (Futar®, Futar® D, Futar® D Fast, Futar® D Slow, Futar® Scan) Bite Registration Materials* are intended for making accurate occlusal records.

Indications for Use

- All Futar bite registration materials (*Futar, Futar D, Futar D Fast, Futar D Slow, Futar Scan*) can be used for making accurate occlusal registrations.
- Futar D materials (*Futar D, Futar D Fast, Futar D Slow*) can be used for applications, which require a hard bite registration silicone.
- *Futar D Fast* can be used for "small applications" because of its shorter working time.
- *Futar D Slow* can be used for time-consuming bite registrations because of its longer working time.
- *Futar Scan* can also be used for an optical registration of occlusal data for CAD/CAM/CIM systems without using powder.

F. Technological Characteristics Summary

The technological characteristics of *Futar® (Futar®, Futar® D, Futar® D Fast, Futar® D Slow, Futar® Scan) Bite Registration Materials* are substantially equivalent to the predicate device technological characteristics. *Futar (Futar, Futar D, Futar D Fast, Futar D Slow, Futar Scan)* and the predicate devices are syringeable, addition-curing, elastomeric materials designed and manufactured for use as bite registration materials.

G. Performance Data

No performance standards have been established for this type of device. *Futar® (Futar®, Futar® D, Futar® D Fast, Futar® D Slow, Futar® Scan) Bite Registration Materials* have been evaluated in accordance with the applicable criteria established in *Guidance for Industry and FDA Staff: Dental Impression Materials – Premarket Notification (FOD#2203, 8/17/1998), ISO 4823 (Dentistry – Elastomeric impression materials):2000/Cor 1:2004/Amd 1:2007*, and *DIN 13903:2005 (Dentistry-Bite registration material)*. The results of device performance testing demonstrated that

*Futar (Futar, Futar D, Futar D Fast, Futar D Slow, Futar Scan)* are suitable for use as bite registration materials. *Futar (Futar, Futar D, Futar D Fast, Futar D Slow, Futar Scan) Bite Registration Materials* have been designed and manufactured to perform in a manner substantially equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2008

Kettenbach GmbH & Company KG
C/O Mr. Stefan Preiss
Responsible Third Party Official
TÜV SÜD America Incorporated
1775 Old Highway 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K081120
Trade/Device Name: Futar® (Futar®, Futar® D, Futar® D Fast, Futar® D Slow, Futar® Scan) Bite Registration Materials
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: April 18, 2008
Received: April 21, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

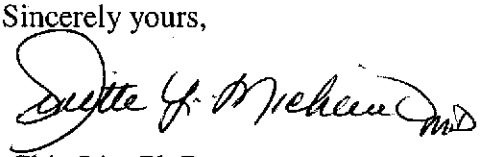
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# SECTION I-D

## Indications for Use

510(k) Number (if known): K081120

Device Name: *Futar® (Futar®, Futar® D, Futar® D Fast, Futar® D Slow, Futar® Scan) Bite Registration Materials*

Indications for Use:

- All Futar bite registration materials (*Futar, Futar D, Futar D Fast, Futar D Slow, Futar Scan*) can be used for making accurate occlusal registrations.
- Futar D materials (*Futar D, Futar D Fast, Futar D Slow*) can be used for applications, which require a hard bite registration silicone.
- *Futar D Fast* can be used for "small applications" because of its shorter working time.
- *Futar D Slow* can be used for time-consuming bite registrations because of its longer working time.
- *Futar Scan* can also be used for an optical registration of occlusal data for CAD/CAM/CIM systems without using powder.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices